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Goro Fujita

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EXAMINER

CROW, ROBERT THOMAS

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,139	Applicant(s) FUJITA, GORO	
	Examiner Robert T. Crow	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 3 April 2007 in which the specification and claims 1-6 were amended, no claims were canceled, and no new claims were added. Claims 7-10 were previously withdrawn. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-6 are under prosecution.

Specification

2. The amendment to the Title of the invention filed 3 April 2007 is acknowledged and entered.

Information Disclosure Statement

3. The Information Disclosure Statement filed 15 February 2007 is acknowledged. However, US 2003-199097 has been lined through because US 2003/0199091 was not published on 18 July 2003, as indicated in the Information Disclosure Statement, nor is Murayama an inventor on US 2003/0199091. In addition, only the abstract of document JP-2000-304688 is being considered because an English language translation of the document has not been provided. See MPEP 609.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite in the recitation "the reaction process" in line 3 of the claim. The recitation "the reaction process" lacks antecedent basis in "a mutual reaction process" as recited in claim 1. It is suggested that "the reaction process" be amended to "the mutual reaction process."

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheppard et al (U.S. Patent No. 6,143,247, issued 7 November 2000).

Regarding claim 1, Sheppard et al teach a disk-shaped bioassay substrate. In a single exemplary embodiment, Sheppard et al teach a platform for affinity-based binding, wherein the platform is a disk (column 3; lines 15-38). Sheppard et al teach the substrate has a detection unit comprising a detection chamber where binding is optically detected (column 34, lines 38-48). The chamber is a data-detecting area comprising a reaction area used for a mutual reaction process of substances to be detected and a target substance. Sheppard et al also teach the data detecting area has a coating of immobilized specific binding agents therein (Figure 1D and column 6, lines 12-25). Immobilized specific binding agents are substances fixed at an end portion, and the area comprising the coating is the detection surface for fixing the substances.

Sheppard et al further teach the detection chamber of Figure 1D (column 21, lines 45-55), wherein the location of the disk having the detection chamber further comprises encoded data in the form of pits

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underneath the detection area (column 22, lines 1-10). Sheppard et al further teach the data pits encode radial positioning information (column 11, lines 45-52). Radial positioning data is positional information. Sheppard et al teach the read functions (i.e., reading of positional information) are performed on the surface of the disk opposite the surface comprising the remaining components of the disk (column 27, lines 32-41). Thus, the opposite area where the read functions are performed is a servo area that is not overlapped with the data detection area.

Sheppard et al also teach the disk-shaped platform further comprises a multiplicity of detection chambers and other components of the invention (column 29, lines 45-50). Thus, the disk of Sheppard et al has a plurality of detection units, each comprising a data detecting area and a servo area as required by the instant claim.

It is noted that the instant claim does not require end portions of the substances to be detected to be fixed; rather, the claim merely requires "a surface for fixing end portions." Thus, the limitation of "a surface for fixing end portions" recites an intended use of the instantly claimed substrate. The courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 1 (e.g., fixing end portions) fail to define additional structural elements to the device of claim 1. Because Sheppard et al teach the structural elements of claim 1, claim 1 is anticipated by Sheppard et al. See MPEP § 2114.

Regarding claims 2-3, Sheppard et al teach the bioassay substrate of claim 1, wherein the reaction area comprises a treated detection surface on which the substances to be detected are fixed; namely, the reaction chamber is coated with a specific binding agent (column 6, lines 13-21). The area comprising the coating is the detection surface for fixing the substances.

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As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claims 2 and 3 (e.g., performing a surface treatment and hybridization) fail to define additional structural elements to the device of claim 1. Because Sheppard et al teach the structural elements of claim 1, claims 2 and 3 are also anticipated by Sheppard et al.

Regarding claim 6, Sheppard et al teach the bioassay substrate of claim 1, wherein the positional information comprises a tracking mark and an address mark; namely, the track widths 72 of Figure 6C are modulated and the geometry of the tracks 75 encode positional information (Figure 6C and column 9, lines 50-60). Thus, the track width 72 is the tracking mark and the track geometry 75 is the positional address mark.

Response to Arguments

Applicant's arguments filed 3 April 2007 (i.e., the "Remarks") have been fully considered but they are not persuasive for the reasons listed below.

Applicant argues on pages 6-7 of the Remarks that Sheppard et al do not teach a servo area optically providing positional information of the data detecting area.

However, as detailed above, Sheppard et al the detection chamber of Figure 1D (column 21, lines 45-55), wherein the location of the disk having the detection chamber further comprises encoded data in the form of pits underneath the detection area (column 22, lines 1-10). Sheppard et al further teach the data pits encode radial positioning information (column 11, lines 45-52). Radial positioning data is positional information.

Sheppard et al teach the read functions (i.e., reading of positional information) are performed on the surface of the disk opposite the surface comprising the remaining components of the disk (column 27, lines 32-41). Thus, the opposite area where the read functions are performed is a servo area that is not overlapped with the data detection area.

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Sheppard et al also teach the disk-shaped platform further comprises a multiplicity of detection chambers and other components of the invention (column 29, lines 45-50). Thus, the disk of Sheppard et al has a plurality of detection units, each comprising a data detecting area and a servo are as required by the instant claim.

8. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hubbard et al (U.S. Patent No. 6,338,820, issued 15 January 2002).

Regarding claim 1, Hubbard et al teach a bioassay substrate. In a single exemplary embodiment, Hubbard et al teach the disc-shaped bioassay substrate (column 8, lines 25-40), comprising a plurality of detection units each comprising a data detecting area used for a mutual reaction of detectable substances and a target substance; namely, concentrically arranged reactions sites 80 of Figure 9B (column 20, lines 21-32) wherein the reaction sites are the data detecting areas. Hubbard et al also teach the data detecting areas 80 of Figure 9B comprise solid support substrates wherein biological probes are affixed (column 19, lines 35-60). Biological probes are substances to be detected that react with target substances. The solid support substrates are the detection surfaces.

Hubbard et al also teach each detection unit of the substrate has a servo are disposed in the area that is not overlapped with the data detecting area and optically providing positional information on the data detecting area; namely, each data detecting area 80 has an identifying mark 82 consisting of a combination of characters and markings (Figure 9B and column 20, lines 21-32).

As noted above in Section 7, the instant claim does not require end portions of the substances to be detected to be fixed; rather, the claim merely requires "a surface for fixing end portions." Thus, the limitation of "a surface for fixing end portions" recites an intended use of the instantly claimed substrate.

As also noted above, in Section 7, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 1 (e.g., fixing end portions) fail to define additional structural

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elements to the device of claim 1. Because Hubbard et al teach the structural elements of claim 1, claim 1 anticipated by Hubbard et al.

Regarding claims 2 and 3, Hubbard et al teach the bioassay substrate of claim 1, wherein the reaction area comprises a treated detection surface on which the substances to be detected are fixed; namely, the data detecting areas incorporate solid support substrates for attachment of probes (column 19, lines 50-62), and the probes are nucleic acid probes for hybridization (column 3, line 63-column 4, line 20). The solid support substrates are the detection surfaces.

As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claims 2 and 3 (e.g., performing a surface treatment and hybridization) fail to define additional structural elements to the device of claim 1. Because Hubbard et al teach the structural elements of claim 1, claims 2 and 3 are also anticipated by Hubbard et al.

Regarding claims 4-5, Hubbard et al teach the bioassay substrate of claim 4, wherein the detection units are arrayed circumferentially; namely, areas 80 are arrayed along the circumference of the substrate in concentric circles (Figure 9B and column 20, lines 21-32).

Regarding claim 6, Hubbard et al teach the bioassay substrate of claim 1, wherein the positional information comprises a tracking mark and an address mark; namely, locating (i.e., identifying) marks comprise an indexing marks to identify the reaction site, which is the address, and a tracking mark (column 6, lines 40-48).

Response to Arguments

Applicant argues on pages 7-8 of the Remarks that Hubbard et al do not teach the claimed detection surface because Hubbard et al does not disclose details of reaction sites 80 of Figure 9B.

However, as noted above, Hubbard et al also teach the data detecting areas 80 of Figure 9B comprise solid support substrates wherein biological probes are affixed (column 19, lines 35-60). Biological probes are substances to be detected that react with target substances, and affixing

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encompasses fixing end portions. Thus, Hubbard et al do teach the data detecting areas comprise a detection surface for fixing end portions of substances to be detected.

In addition, as also noted above, the instant claim does not require end portions of the substances to be detected to be fixed; rather, the claim merely requires "a surface for fixing end portions." Thus, the limitation of "a surface for fixing end portions" recites an intended use of the instantly claimed substrate.

Further, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 1 (e.g., fixing end portions) fail to define additional structural elements to the device of claim 1. Because Hubbard et al teach the structural elements of claim 1, claim 1 anticipated by Hubbard et al.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jehanne Sitton
JEHANNE SITTON
PRIMARY EXAMINER
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Robert T. Crow
Examiner
Art Unit 1634

Robert T. Crow